UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

APOTEX, INC, Plaintiff, v. DAIICHI SANKYO, INC. and DAIICHI SANKYO CO., LTD. Defendants.	)	12-cv-9295 Judge Sharon Johnson Coleman

MEMORANDUM OPINION AND ORDER

The defendants Daiichi Sankyo Co. Ltd. and Daiichi Sankyo, Inc. (collectively "Daiichi") listed United States Patents Nos. 6,878,703 (the "'703 Patent") and 5,616,599 (the "'599 Patent") in connection with their new drug Benicar, consisting of olmesartan medoxomil. Daiichi Sankyo, Co., Ltd. is a Japanese pharmaceutical company and the parent company to Daiichi Sankyo., Inc. This case involves Plaintiff Apotex, Inc.'s ("Apotex") efforts to obtain the Food and Drug Administration's ("FDA") approval to market a generic version of Daiichi's Benicar drug. Apotex seeks a declaratory judgment of noninfringement of the '703 Patent. Pursuant to Fed. R. Civ. P. 12(b)(1), Daiichi moves to dismiss Apotex's amended complaint for lack of subject matter jurisdiction. For the following reasons, Daiichi's motion to dismiss is granted in its entirety.

Background

1. Statutory Framework

The Hatch-Waxman Act (the "Act") governs the FDA's approval process for prescription drugs. The Act was created to "'strike a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.'" *Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008) (citing *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002)). Pursuant to the Act, brand-name (or "pioneering") pharmaceutical companies seeking to market new, previously unapproved drugs are required to file a New Drug Application ("NDA") with the FDA. *Seattle Children's Hosp. v. Akorn, Inc.*, No. 10-CV-5118, 2011 U.S. Dist. LEXIS 145998 at *2 (N.D. Ill. Dec. 20, 2011); *see also* 21

U.S.C. § 355(a), (b). As part of the NDA process, a pioneering drug company must submit information regarding the new drug's safety and efficacy obtained from clinical trials. 21 U.S.C. § 355(b)(1). The pioneering drug company must also provide the FDA with information including "all patents covering its drug or the methods of using the drug with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.'" *Caraco Pharm. Labs.*, 527 F.3d at 1282 (citing 21 U.S.C. § 355 (b)(1), (c)(2)). The FDA lists these patents provided by the drug company in a publication called the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 USC § 355(j)(2)(A)(i). Drugs approved by the FDA are known as "listed drugs." *Id*.

To encourage the development of generic versions of listed drugs, the Hatch-Waxman Act provides for an expedited and far cheaper approval process for generic versions of patented drugs to enter the market. This process is known as the "Abbreviated New Drug Application" ("ANDA"). *Caraco Pharm. Labs.*, 527 F.3d at 1282. Under the ANDA process, generic drug companies are not required to conduct their own independent clinical trials to prove the safety and efficacy of their drugs. 21 U.S.C. § 355(j)(2)(A)(iv). Instead generic drug companies can rely on the research of a pioneering pharmaceutical company so long as the generic drug company demonstrates that its generic drug product is the "bioequivalent" to a NDA listed drug. *Id*. An ANDA applicant must also submit one of four certifications addressing each of the patents listed in the Orange Book that cover the relevant listed drug. 21 U.S.C. §355(j)(2)(A)(vii). Specifically the ANDA filer must certify that either: (I) no patent information has been filed with the FDA; (II) the patent has expired; (III) the patent will expire on a particular date and approval of the ANDA should be deferred until expiration; or (IV) in the opinion of the ANDA applicant, the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. *Seattle Children's Hosp.*, 2011 U.S. Dist. LEXIS 145998 at *3. A certification that an Orange-Book-listed patent is invalid or not infringed is commonly known as a "Paragraph IV" certification. Where an ANDA contains a Paragraph IV certification, the timing of approval depends on two events: (i) whether the holder of the listed patent brings an infringement suit within 45 days of receiving notice of the ANDA filing, and (ii) whether the company seeking approval was the first to file an ANDA with a Paragraph IV certification to the listed patent. *Id*. at *4; *see also* 21 USC 355(j)(5)(B)(iii).

The Hatch-Waxman Act provides that the mere act of filing a Paragraph IV ANDA for a listed drug constitutes an act of patent infringement. *Caraco Pharm. Labs.*, 527 F.3d at 1283. If a patentee or NDA holder does not bring suit within 45 days of receiving notice of a Paragraph IV certification filing, the FDA will approve the ANDA immediately. If the pioneering drug company does bring suit within 45 days, the FDA may not approve the ANDA for 30 months, unless a court decides that the patent(s)-in-suit are invalid or not infringed. *Seattle Children's Hosp.*, 2011 U.S. Dist. LEXIS 145998 at *4. Where a generic company is the first to file an ANDA Paragraph IV certification for a listed patent, the Hatch-Waxman Act grants that company a 180-day period of generic marketing exclusivity during which time the FDA will not approve a later filed Paragraph IV ANDA based on the same NDA. In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") which amended the Hatch-Waxman provisions governing the commencement of the 180-day exclusivity period. *Id*. at *5. After the enactment of the MMA, the exclusivity period can only be triggered by the first-filer's commercial marketing of its generic drug product. However, under the MMA, there is now a forfeiture provision. The first-filer of a Paragraph IV ANDA may forfeit its exclusivity period if a subsequent ANDA filer obtains a final judgment of invalidity or noninfringement. *Id*.

2. Factual Background

Daiichi holds an approved NDA for Benicar, a drug used for the treatment of high blood pressure. As part of the process for filing its Benicar NDA, Daiichi listed Patents '599 and '703 in the FDA's Orange Book in connection with its NDA No. 21-286. The first ANDA applicant to file a Paragraph IV certification for Daiichi's '599 and '703 patents was Mylan Laboratories, Ltd. ("Mylan").[1] Accordingly, Mylan is entitled to 180 days of market exclusivity regardless of whether it established that the Orange Book patents were invalid or not. *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008) (noting that "[a]ll that is required for the first Paragraph IV ANDA filer to receive the 180-day exclusivity period is that it submits a substantially complete ANDA that contains a Paragraph IV Certification"). The start of the 180-day exclusivity period can only be triggered by Mylan's marketing of its generic drug. 21 U.S.C. § 355(j)(5)(B)(iv). If however, a subsequent filer obtains a final judgment of invalidity or

[1] Mylan is presently not a party in this case. Mylan has moved to intervene and has filed its own motion to dismiss should this Court grant its motion to intervene.

noninfringement, Mylan must begin marketing within 75 days or forfeit its exclusivity period. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA); *see also Seattle Children's Hosp.*, 2011 U.S. Dist. LEXIS 145998 at *5-6.

After Mylan filed its Paragraph IV ANDA regarding both Patents '703 and '599, Daiichi sued Mylan on July 31, 2006 for infringement of the '599 patent in a district court in New Jersey. Prior to suing Mylan regarding the '599 patent, Daiichi statutorily disclaimed every claim of the '703 patent pursuant to 35 U.S.C. § 253. Eventually the district court found that the '599 patent was valid and that Mylan infringed the '599 patent. Mylan never brought a declaratory judgment action regarding the disclaimed '703 patent. In the instant case, Apotex seeks a final judgment of invalidity or noninfringement regarding the '703 patent in the hopes of compelling Mylan to begin marketing within 75 days or forfeiting its exclusivity period. Daiichi moves to dismiss Apotex's complaint for lack of subject matter jurisdiction. Daiichi argues that there is no case or controversy here because the '703 patent was disclaimed. Apotex argues that despite Daiichi's disclaimer, the '703 patent continues to exclude competition in the market because it remains listed in the FDA's Orange Book.

Legal Standard

Pursuant to Fed. R. Civ. P. 12(b)(1), a court must dismiss any action for which it lacks subject matter jurisdiction. Rule 12(b)(1) motions are premised on either facial or factual attacks on jurisdiction. *Simonian v. Oreck Corp.*, No. 10 C 1224, 2010 U.S. Dist. LEXIS 86832, at *3-4 (N.D. Ill. Aug. 23, 2010). If the defendant makes a factual attack on the plaintiff's assertion of subject matter jurisdiction, it is proper for the court to look beyond the jurisdictional allegations in the complaint and to view whatever evidence has been submitted in response to the motion. *Id*. The plaintiff must then put forth "competent proof" that the court has subject matter jurisdiction. *NLFC, Inc. v. Devcom Mid-America, Inc.*, 45 F.3d 231, 237 (7th Cir. 1995).

Federal courts have subject matter jurisdiction over declaratory judgment actions brought by Paragraph IV ANDA filers to establish noninfringement or invalidity of Orange-Book-listed patents to the extent that they present an Article III case or controversy. *Caraco Pharm. Labs.*, 527 F.3d at 1285; *see also* 31 U.S.C. § 271(e)(5). To determine whether a declaratory judgment action satisfies the Article III case or controversy requirement, the court must inquire as to "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality

to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (U.S. 2007). "[A]n action is justiciable under Article III only where (1) the plaintiff has standing, *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992), (2) the issues presented are ripe for judicial review, *Abbott Labs. v. Gardner*, 387 U.S. 136, 149, 87 S. Ct. 1507, 18 L. Ed. 2d 681 (1967), and (3) the case is not rendered moot at any stage of the litigation, *United States Parole Comm'n. v. Geraghty*, 445 U.S. 388, 397, 100 S. Ct. 1202, 63 L. Ed. 2d 479 (1980)." *Caraco Pharm. Labs.*, 527 F.3d at 1291; *see also Seattle Children's Hosp.*, 2011 U.S. Dist. LEXIS 145998, at *13.

In order to have standing, a party must demonstrate: (1) an alleged injury in fact, a harm suffered by the plaintiff that is concrete and actual or imminent; (2) causation, a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant; and (3) redressability, a likelihood that the requested relief will redress the alleged injury. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008). "The Federal Circuit has recognized, in the context of the Hatch-Waxman Act, that the creation of 'an independent barrier to the drug market' by a brand drug company 'that deprives [the generic company] of an economic opportunity to compete' satisfies the injury-in-fact and causation requirements of Article III standing." *Seattle Children's Hosp. v. Akorn, Inc.*, No. 10-CV-5118, 2011 U.S. Dist. LEXIS 145998, at *15 (N.D. Ill. Dec. 20, 2011) (citing *Caraco*, 527 F.3d at 1285 and *Prasco*, 537 F.3d at 1339).

Discussion

Daiichi moves to dismiss Apotex's complaint arguing that there can be no justiciable dispute concerning a disclaimed patent. Apotex concedes that the '703 patent is no longer enforceable, but argues that it continues to exclude competition in the market and continues to have preclusive effect. (Apotex Resp. at 1 and 5). Apotex argues that because a judgment has never been entered stating that the '703 patent is invalid, the '703 patent prevents it from selling its competing generic version of the Benicar drug until the end of Mylan's 180 day exclusivity period.

The Federal Circuit has recognized that prior to the "2003 [MMA] amendments, 'NDA holders employed several methods of delaying the early resolution of patent disputes.'" *Dey Pharma, LP v. Sunovion Pharms., Inc.*, 677 F.3d 1158, 1160 (Fed. Cir. 2012) (citing *Janssen Pharmaceutica, N.V. v. Apotex*, Inc., 540 F.3d 1353, 1357 (Fed. Cir. 2008). In some cases where

NDA patent holders listed multiple patents in the FDA's Orange Book, NDA holders developed a strategy where they would initiate suit on only one of the patents after receiving notice of a Paragraph IV ANDA filing. This would entitle the NDA holder to a 30-month stay before FDA approval of the generic drug. Moreover, even if the one patent sued on was found invalid or not infringed by the generic drug, the ANDA filer would still run the risk of infringing on the other patents implicated, but not sued on by the NDA holder. "To address this problem Congress specified that an ANDA filer who is not sued within 45 days could bring a declaratory judgment action under 28 U.S.C. § 2201 against the NDA holder." *Dey Pharma*, 677 F.3d at 1160-1161 (citing 21 U.S.C. § 355(j)(5)(C)). These amendments also protect subsequent ANDA filers' interest in the early resolution of patent rights due to the 180-day exclusivity period afforded successful first ANDA filers. "If the first ANDA filer 'parked' its 180-day exclusivity under an agreement with the brand-name company, a subsequent ANDA filer could independently trigger the first filer's exclusivity period through a declaratory judgment action leading to a final judgment of invalidity or noninfringement, thereby accelerating the second ANDA filer's ability to market its drug." *Dey Pharma*, 677 F.3d at 1160-1161.

Here, Patent '703 does not create an independent barrier that deprives Apotex of an economic opportunity to compete. Because Daiichi disclaimed all claims associated with the '703 Patent pursuant to 35 U.S.C. § 253, both Daiichi and Apotex no longer hold any meaningful interest in the now disclaimed patent. "Disclaiming particular claims under § 253 'effectively eliminate[s] those claims from the original patent.'" *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1299 (Fed. Cir. 2011) (*citing Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998)). "In other words, upon entry of a disclaimer under § 253, we treat the patent as though the disclaimed claim(s) had 'never existed.'" *Genetics Inst.*, 655 F.3d at 1299; *see also Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996). Apotex concedes that the '703 patent was statutorily disclaimed and does not dispute the effects of such a disclaimer. Nevertheless, Apotex argues that this Court must still decide whether its generic drug infringes on the non-existent '703 patent because the patent remains listed in the Orange Book. Daiichi, however, requested that the FDA delist the '703 Patent on July 11, 2006. It is unclear why the FDA has yet to actually remove the patent from the Orange Book.

Apotex relies on *Caraco Pharm. Labs.*, 527 F.3d 1278, to support its argument that there is jurisdiction where a first ANDA filer has not begun its exclusivity period and a subsequent

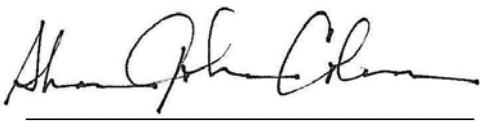
ANDA filer seeks a declaratory judgment of noninfringement to eliminate an independent barrier to regulatory approval. *Caraco*, however, is distinguishable from the case at hand by the important fact that the patent at issue in that case was never disclaimed. The Federal Circuit held that by preventing the FDA from approving ANDAs of generic drug manufacturers, the NDA holder was effectively excluding Caraco from offering what it claimed to be a non-infringing generic drug. Unlike *Caraco*, there is no such exclusion in the instant case. Daiichi is not preventing the FDA from approving Apotex's ANDA through any delay tactics or strategies similar to the NDA holder's covenant not to sue in *Caraco*. Moreover, all parties acknowledge that Daiichi can never assert the '703 patent against any ANDA filer or any entity as the patent no longer exists by virtue of Daiichi's disclaimer of all claims associated with the patent. The mere fact that the FDA has failed for some reason to delist Patent '703, despite Daiichi's request, does not create a case or controversy by which Apotex may seek a declaratory judgment regarding a nonexistent patent. Daiichi disclaimed Patent '703 and properly requested that the Orange Book be updated to reflect Daiichi's disclaimer. Although in *Seattle Children's Hosp.*, 2011 U.S. Dist. LEXIS 145998, the court held that notwithstanding an NDA holders unilateral covenant not to sue, a case or controversy continued to exist between the parties because of the continued listing of the patent in the FDA's Orange Book; in that case, again, the listed patent was never disclaimed. Accordingly, in that case, the patent actually served as an independent barrier to the approval of the defendant's ANDA. Here, the '703 patent continues to be listed, by no error on Daiichi's part, even though the patent was disclaimed. This is insufficient to meet the case and controversy standing requirements under Article III.

Conclusion

For the foregoing reasons, Daiichi's motion to dismiss is granted in its entirety. Given this Court's ruling granting Daiichi's motion to dismiss, non-party Mylan's motions are moot.

IT IS SO ORDERED.

Date: January 9, 2014



Sharon Johnson Coleman
United States District Judge